

## REMARKS

### 1. Preliminary Remarks

#### a. Status of the Claims

Claims 23, 25, 31, 33, 39 and 40 are pending in this application. Claims 23, 39 and 40 are amended. Claims 25 and 33 are allowed. Applicant respectfully requests entry of the amendments and remarks made herein into the file history of the application. Upon entry of the amendments, claims 23, 39, and 40 will be pending and under active consideration.

#### b. Amendment to the Claims

Claim 23 is amended to be directed to an isolated nucleic acid, wherein the sequence of the nucleic acid is selected from the group consisting of 1. group consisting of: (a) SEQ ID NO: 348; (b) nucleotides 1-21 of SEQ ID NO: 348; (c) nucleotides 1-22 of SEQ ID NO: 348; (d) a sequence of 23-24 nucleotides, wherein nucleotides 1-22 of said sequence consist of SEQ ID NO: 348; (e) a DNA encoding the nucleic acid of any one of (a)-(d), wherein the DNA is identical in length to (a)-(d), respectively; and the complement of any one of (a)-(c), wherein the complement is identical in length to (a)-(c), respectively. Support for a “nucleotides 1-21 of SEQ ID NO: 348,” “nucleotides 1-22 of SEQ ID NO: 348,” and “a sequence of 23-24 nucleotides, wherein nucleotides 1-22 of said sequence consist of SEQ ID NO: 348,” can be found throughout the specification, for example, at paragraph [0284], which states the following:

The 3' terminus of observed GAM RNA sequences is often truncated or extended by one or two nucleotides.

The GAM RNA is the miR sequence as set forth in SEQ ID NO: 348, which is a 22-mer. One or two nucleotide extensions would create a sequence of 23-24 nucleotides in which nucleotides 1-22 of said sequence consist of SEQ ID NO: 348. One or two nucleotide truncations would create a nucleic acid having nucleotides 1-21 and 1-22 of SEQ ID NO: 348, respectively. As supported by the specification, miR with either one or two nucleotide truncations or extensions at the 3' of a miR sequence are contemplated by Applicant. Applicant submits that the specification reasonably conveys to one of skill in the art that the inventors, at the time of the invention, has possession of the parts (c) and (d) of amended claim 23.

In order to expedite prosecution, and without prejudice to seeking claims of similar scope in a continuing application, claims 39 and 40 are amended to be directed to a probe consisting of a

human insert, wherein the human insert consists of the sequence of the nucleic acid of claim 23 or 25. Support for the amended probe language can be found throughout the specification, for example, at paragraph 0035.

**c. Claim Objections**

On page 3 of the Office Action, the Examiner objects to the typographical error “acide” in claim 39. Claim 39 has been amended to remove this term thereby overcoming the claim objection.

**2. Patentability Remarks**

**a. 35 U.S.C. §112, First Paragraph, Written Description**

On pages 3-8 of the Office Action, the Examiner rejects claims 23, 31 and 39 under 35 U.S.C. §112, first paragraph, for allegedly lacking proper written descriptive support. The Examiner asserts that there is no disclosure showing or suggesting that each particular mature miRNA identified in the program can perform the same function as an miRNA as any 19, 20, 23 or 24 nucleotide fragment thereof, much less any 19, 20, 23, or 24 nucleotide fragment that is only 80% identical to the actual predicted sequence of SEQ ID NO: 348. Applicant respectfully disagrees.

As shown in Table 6 of the instant application as provided above in the Amendment to the Specification, there is a large amount of data showing target gene sequences that are bound by the GAM RNA as set forth in SEQ ID NO: 348 with less than 80% sequence identity between the miR sequence and the target sequence. Certainly, therefore, 80% variants or higher of SEQ ID NO: 348 would be able to bind and suppress target gene mRNA translation. As stated above, however, Applicant has deleted 80% variants from claim 23 to expedite prosecution.

Similarly, the data also shows that 3' truncations or extensions of SEQ ID NO: 348 would still enable the fragment to bind a target gene mRNA sequences and suppress translation. Table 6 sufficiently describes these fragments or variants of SEQ ID NO: 348 to perform the same function as a miRNA. If these nucleic acids are described, the probes consisting and the vectors comprising these nucleic acids are also described. In view of the foregoing amendment and remarks, Applicant submits that the one of skill would conclude that the Applicant was in possession of the claimed invention. Therefore, Applicant respectfully submits that the rejection of claims 23, 31 and 39 under 35 U.S.C. §112, first paragraph, for allegedly lacking proper written descriptive support, is overcome and should be withdrawn.

**b. 35 U.S.C. §102, Anticipation***§102(b)---Dunn*

On pages 8 and 9 of the Office Action, the Examiner rejects claims 39 and 40 under 35 U.S.C. §102(b) as being anticipated by GenBank Accession No. AZ593982 (hereafter “Dunn”) teaches a 701 insert that comprises SEQ ID NO: 348 and 4233864. The Examiner asserts that the term “insert” clearly implies a probe may contain one or more additional nucleotides on one or both sides of “the human insert” and there is no language excluding the additional one or more nucleotides from being human nucleotides. Applicant respectfully disagrees.

The language “human insert consist of the sequence of the nucleic acid of claim 23 or 25” clearly provides the parameters that the insert has no additional nucleotides on one or both sides of the human insert. The term consist means that sequence and no other sequence but the nucleic acids of claim 23 or 25 are to define the insert. Applicant is at a loss for the Examiner’s definition of the term “insert” and lack of guidance in this matter. Nevertheless, in order to expedite prosecution, Applicant has amended claims 39 and 40 to a probe consisting of a human insert in order to remove any doubt from the Examiner that the probe is only the nucleic acid of claims 23 or 25. In view of the foregoing amendment and remarks, Applicant respectfully submits that the rejection of claims 39 and 40 under 35 U.S.C. §102(b) over Dunn has been overcome and should be withdrawn.

*§102(b)---Birren*

On page 9 of the Office Action, the Examiner rejects claims 39 and 40 under 35 U.S.C. §102(b) as being anticipated over GenBank Accession No. AC015918 (hereafter “Birren”). Specifically, the Examiner asserts that the 220,581 nucleotide insert of Birren comprises SEQ ID NO: 384 and SEQ ID NO: 4233864. The Examiner asserts that the term “insert” clearly implies a probe may contain one or more additional nucleotides on one or both sides of “the human insert” and there is no language excluding the additional one or more nucleotides from being human nucleotides. Applicant respectfully disagrees.

As discussed above, claims 39 and 40 are amended to clearly exclude a 220,581 nucleotide insert. In view of the foregoing amendment, Applicant respectfully submits that the rejection of claims 39 and 40 under 35 U.S.C. §102(b) over Birren has been overcome and should be withdrawn.

*§102(e)---Tuschl*

On pages 10 and 11 of the Office Action, the Examiner rejects claims 23, 31, and 39 under 35 U.S.C. §102(e) as being anticipated over U.S. Patent No. 7,232,806 (hereafter “Tuschl”).

Specifically, the Examiner asserts that Tuschl discloses a 21 nucleotide sequence that has at least 17 nucleotides in common with instant SEQ ID NO: 348 and therefore this sequence is at least 80% identical to SEQ ID NO: 348. Applicant respectfully disagrees.

The Examiner has failed to appreciate the full scope of the claim. Specifically, part (c) of claim 23 was directed to “a sequence at least 80% identical to (a) or (b), wherein the sequence is 19-24 nucleotides in length.” Tuschl does disclose a 21 nucleotide sequence and therefore satisfied the wherein clause of part (c) of claim 23. However, Tuschl does not teach a sequence that is 80% identical to SEQ ID NO: 384. SEQ ID NO: 384 is 22 nucleotides in length. Tuschl has only 17 nucleotides in common with the 22-mer of SEQ ID NO: 384, which is only 77% identical to (a) and therefore fails the first part of section (c) of claim 23. Nevertheless, as stated above, in order to expedite prosecution, Applicant has removed 80% variant from claim 23. Tuschl does not teach or suggest SEQ ID NO: 348 or a 21, 22, 23, or 24-mer of SEQ ID NO: 348. Therefore, Tuschl does not anticipate amended claim 23, and its dependent claims 31 and 39. In view of the foregoing amendment and remarks, Applicant submits that the rejection of claims 23, 31, and 39 under 35 U.S.C. §102(e) over Tuschl is overcome and should be withdrawn.

**c. 35 U.S.C. §103(a), Obviousness**

*Zhou*

On pages 11-15 of the Office Action, the Examiner rejects claims 23, 31, and 39 under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 7,250,289 (hereafter “Zhou”). Specifically, the Examiner asserts that Zhou discloses an array probe (SEQ ID NO: 669995) that is at least 80% identical to SEQ ID NO: 348 and its complements. Applicant respectfully disagrees.

Applicant submits that there are no blaze marks whatsoever in Zhou’s 982,914 SEQ ID NOs and countless permutations of their length to identify the genus of 80% variants of SEQ ID NO: 384. Nevertheless, in order to expedite prosecution, 80% variants has been deleted from claim 23. Zhou fails to teach or suggest any sequence that remotely has the nucleotide sequence of SEQ ID NO: 384 or vector and probe having this sequence. Therefore, in view of the foregoing amendment and remarks, Applicant submits that the rejection of claims 23, 31, and 39 under 35 U.S.C. §103(a) has been overcome and should be withdrawn.

*Tuschl*

On pages 15 and 16 of the Office Action, the Examiner rejects claims 23, 31, and 39 under 35 U.S.C. §103(a) as being obvious over Tuschl. Specifically, the Examiner asserts that Table 2 of Tuschl discloses a mature 22-mer miRNA that has 17 nucleotides in common with instant SEQ ID

NO: 348. Tuschl further asserts 80% variants of any sequence in Table 2 as well as miRNAs having a length of 19-24 nucleotides, particular 21, 22 or 23 nucleotides. The Examiner concludes that it would have been obvious to make and use any of the disclosed sequences since Tuschl taught any of the sequence can be used for regulation of gene expression or detection of miRNAs.

In view of the foregoing amendments, Applicant submits that Tuschl does not teach or suggest SEQ ID NO: 348 or fragments thereof. Therefore, the rejection of claims 23, 31, and 39 under 35 U.S.C. §103(a) as being obvious is overcome and should be withdrawn.

### 3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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